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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,775	01/23/2002	Steven Mark Eker	SRI/4578-2	8753

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EXAMINER

ZHOU, SHUBO

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/055,775	<b>Applicant(s)</b> EKER ET AL.	
	<b>Examiner</b> Shubo (Joe) Zhou	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 99-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 99-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' amendment and request for reconsideration filed 10/21/05 are acknowledged. Applicants' arguments have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections are either reiterated or newly applied, and constitute the complete set presently being applied to the instant application. Rejections and/or objections not reiterated from the previous office action are hereby withdrawn.

Claims 1-22 and 99-104 are currently pending and under consideration.

#### ***Sequence Rule Compliance***

Upon further consideration, it is noted that there are no sequence disclosures in the application that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). Thus, the sequence rule compliance requirement set forth in the previous Office action mailed 6/21/05 is hereby withdrawn.

#### ***Oath/Declaration***

It is noted that the oath/declaration filed 1/23/02 was not signed. An Office letter requesting a signed oath/declaration was mailed 2/20/02. While the transmittal letter of applicants' response filed 6/20/02 indicated "a combined declaration and power of attorney in compliance with 37 CFR 1.63" was submitted, no such declaration is seen in the file of the application. Applicants are requested to provide a signed oath/declaration.

*Claim Rejections-35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 and 99-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claims 1, 12, and 99 are amended to recite “a method for evaluating at least one metabolic pathway and culturing cells” and a step of “culturing cells in a medium selected based upon identification of one of the first and second sets to selectively support viability of the cells.” Applicants state that support for the “culturing” step is found on page 6 of the specification. Examination of the specification reveals that while the specification does recite, on page 6, “culturing” cells, it is “culturing the first and/or second living cell under culture conditions in which one or more compounds of the minimal set of transportable compounds is withheld.” Given that this “culturing” is to culture the first and/or second living cell” and it is “under culture conditions in which one or more compounds of the minimal set of transportable compounds is withheld,” and that it is not clear what is meant by “conditions in which one or more compounds of the minimal set of transportable compounds is withheld” (Does “withheld” mean that the one or more compounds are in or out of the culture conditions?), it is deemed that the “culturing” step disclosed on page 6 of the specification is distinct from the “culturing” step

recited in the claims, which is “culturing cells in a medium selected based upon identification of one of the first and second sets to selectively support viability of the cells.” The limitation added to the claims is thus new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 and 99-104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of each of independent claims 1, 12, and 99 is amended to recite “a method for evaluating at least one metabolic pathway and culturing cells.” The “evaluating” involves machine-based symbolic modeling and the “culturing” involves wet-lab culture of cells. It is not clear what is the relationship, if any, between the method of evaluating modeling and the culturing of cells. There is no clear indication that the cells being cultured are the cells in which the pathway is evaluated. While the “culturing” step recites “selected based upon identification of one of the first and second sets,” it is unclear as to whether the “identification” is done to the cells being cultured.

Furthermore, the “evaluating” step in lines 5-8 of claim 1 identifies “a first set of precursor substrates and/or chemical reactions” or “a second set of precursor substrates and/or chemical reactions.” Thus, only one set is produced, the first set or the second set. However, confusingly, “both” sets are required in the medium selection in the last two lines of the claim. These set citations conflict as to what sets are meant in the last two lines of claim 1 vs only one set being produced in the evaluating step. This confliction also exists in the other independent claims as

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follows: Claim 12 cites alternative “and/or” in line 12, wherein the “or” alternative also conflicts with the “and” requirement in the last two lines of the claim. Claim 99 is confusing for the same “and/or” citation as claim 12.

The phrase “the identified set of precursor substrates” recited in claim 2 lacks clear antecedent basis. There are different multiple “sets” of precursor substrates identified: “a first set of precursor substrates” and “a second set of precursor substrates.” It is not clear what set of precursor substrates is referred to in claim 2.

***Claim Rejections-35 USC § 102***

• The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Darnell et al. (Molecular Cell Biology, 1987).

Darnell et al. present models for the chemical pathway of protein synthesis (pages 53-63, and 106-124), evaluate the models and identify sets of precursor substrates such as 20 amino acids required to synthesize a protein molecule (pages 54 and 109) and culture cells with medium selected based on identification of the sets of substrates, wherein the medium comprises the amino acids that are required substrates of protein synthesis (pages 192-200). It is pointed out

that due to absence of an explicit definition for the term “symbolic model” in the specification, the models of graphs and symbols disclosed by Darnell et al. are interpreted as symbolic models.

As to claim 2, the amino acids identified are a minimal set for protein synthesis because other substrates are also required such as mRNA and enzymes. See pages 122-123. As to claims 3-4, Darnell et al. identified multiple sets of substrates such as a set of amino acids, a set of nucleic acids, a set of enzymes, etc. that, altogether, are sufficient for protein synthesis. As to claim 5, prior to evaluating the necessary amino acid synthesis, Darnell et al. present a model for protein synthesis that reduces the elements to ribosomes, which are sites for protein synthesis. See pages 116-117. As to claim 11, while Darnell et al. do not explicitly recite 100 or more reactions in the protein synthesis pathways, it is inherent that since the pathway includes reactions of synthesis of each of the 20 amino acids and reactions of synthesis of each of the astronomical number of different mRNAs and enzymes that are required for protein synthesis, it would be readily recognized by one skilled in the art that the reactions involved in protein synthesis are at least 100.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136 (a). A shortened statutory period for response to this final action is set to expire three months

from the date of this action. In the event a first response is filed within two months of the mailing date of this final action and the advisory action is not mailed until after the end of the three-month shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than six months from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also



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Shubo (Joe) Zhou, Ph.D.



Patent Examiner

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER